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| APPLICATION NO.          | FILING DATE                           | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--------------------------|---------------------------------------|-------------------------|-------------------------|------------------|
| 09/678,486               | 10/04/2000                            | Geoffrey Thomas Andrews | 1652-11                 | 8045             |
| 23117 7                  | 7590 05/21/2003                       |                         |                         |                  |
| NIXON & VANDERHYE, PC    |                                       | EXAMINER                |                         |                  |
| 1100 N GLEB<br>8TH FLOOR |                                       |                         | THOMPSON, MICHAEL M     |                  |
| AKLINGTON                | , VA 22201-4714                       |                         | ART UNIT                | PAPER NUMBER     |
|                          |                                       |                         | 3763                    | / 1              |
|                          |                                       |                         | DATE MAILED: 05/21/2003 | ι ,              |
|                          | · · · · · · · · · · · · · · · · · · · | pe <sup>der'</sup>      |                         |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application N .  | Applicant(s)   | Gl       |  |  |  |
|---|--|--|----------|--|--|--|
|   | 09/678,486   | ANDREWS ET AL.   |          |  |  |  |
| Offic Action Summary  | Examiner   | Art Unit   |          |  |  |  |
|   | Michael M. Thompson  | 3763   |          |  |  |  |
| The MAILING DATE of this communication app<br>Period f r Reply  | pears on the cover sheet with the c  | correspondence address   |          |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status | 36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communic D (35 U.S.C. § 133). | cation.  |  |  |  |
| 1) Responsive to communication(s) filed on 05 /   | <u>March 2003</u> .  |  |          |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Th  | is action is non-final.  |  |          |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |  |  |          |  |  |  |
| 4)⊠ Claim(s) <u>16-25</u> is/are pending in the application   | on.  |  |          |  |  |  |
| 4a) Of the above claim(s) is/are withdray   |  |  |          |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |          |  |  |  |
| 6)⊠ Claim(s) <u>16-25</u> is/are rejected.  |  |  |          |  |  |  |
| 7) Claim(s) is/are objected to.   |  |  |          |  |  |  |
| 8) Claim(s) is are subject to restriction and/or election requirement.  |  |  |          |  |  |  |
| Application Papers  |  |  |          |  |  |  |
| 9)☐ The specification is objected to by the Examine   | r.   |  |          |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |  |  |          |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |  |          |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |  |  |          |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |  |  |          |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |  |  |          |  |  |  |
| Pri rity under 35 U.S.C. §§ 119 and 120   |  |  |          |  |  |  |
| 13) Acknowledgment is made of a claim for foreign   | n priority under 35 U.S.C. § 119(a   | ı)-(d) or (f).   |          |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |  |  |          |  |  |  |
| 1. Certified copies of the priority documents   | s have been received.  |  |          |  |  |  |
| 2. Certified copies of the priority documents   | s have been received in Applicati  | on No  |          |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |  |  |          |  |  |  |
| 14) Acknowledgment is made of a claim for domesti   | ·  |  | cation)  |  |  |  |
| <i>.</i> •  | •  |  | oution). |  |  |  |
| <ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>  |  |  |          |  |  |  |
| Attachment(s)   |  |  |          |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>  | 5) Notice of Informal  | y (PTO-413) Paper No(s)<br>Patent Application (PTO-152)  |          |  |  |  |
| J.S. Patent and Trademark Office PTO 326 (Pay 04 01)  | tion Summany   | Part of Paper No. 11   |          |  |  |  |

Application/Control Number: 09/678,486 Page 2

Art Unit: 3763

#### **DETAILED ACTION**

## Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or a submitted PTO-1449, they have not been considered.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 16-19, 21-22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook (4,637,396). Cook teaches a hollow radially expandable balloon member having terminal portions with a diameter smaller than an intermediate portion, a fluid impervious polyurethane wall wherein the wall has reinforcing fibers integrally with the wall material, a catheter having a tube portion whereby the balloon member can be inflated and deflated by the catheter or tube portion limit radial expansion of the balloon device. Cook further teaches Dacron or Kevlar as a possible fiber filament material among others.

Application/Control Number: 09/678,486 Page 3

Art Unit: 3763

## Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Breslow (3,616,199). Cook teaches all of the limitations of the claims except for the reinforcing fibers being made of a polyester polymer. Breslow teaches a fibrous polyester reinforcing material to a rubber stock such as polyurethane. It would have been obvious to one of ordinary skill in the art, at the time of invention to have simply substituted or modified the reinforcing fibers taught by Cook with the reinforcing fibers and materials taught by Breslow for the well known purpose of enhancing the strength and stiffness of the inflated balloon taught by Cook.

Application/Control Number: 09/678,486

Art Unit: 3763

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook. Cook teaches limiting radial expansion of the intermediate portion. Cook does not expressly disclose that the limit of radial expansion is not more than 115% of the maximum unstretched radially expanded state. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have provided that the maximum limit of radial expansion to not more than 115% of the maximum unstretched radially expanded state because Applicant has not disclosed that limiting radial expansion to not more than 115% provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with limiting radial expansion to not more than any reasonable percent or not more than specifically 115%. Therefore, it would have been an obvious matter of design choice to modify Cook to obtain the invention as specified by Applicant for the well known purpose of preventing over-expansion of a balloon device within the vasculature of a patient to prevent rupture or tearing of the vessel.

#### Response to Arguments

8. Applicant's arguments, see pages 6 and 7, filed 03-05-03, with respect to the rejection(s)of previous claim(s) 1-14 under 35 U.S.C. 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Cook as recited supra.

Application/Control Number: 09/678,486

Art Unit: 3763

#### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for submissions to the organization where this application or proceeding is assigned is (703) 872-9302. The official fax phone number for submission of After Final response is (703) 872-9303.

Michael M. Thompson

**Patent Examiner** 

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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May 19, 2003